

The Nivaggioli reference discloses methods of forming a coating for pharmaceutical doses where the coating includes alginates and/or gellan gum. Nivaggioli was specifically searching for coating materials that would provide a good appearance and improved mouth feel.

The Office Action asserts that because both shellac and alginate were known materials used to coat food and pharmaceutical doses, one of ordinary skill in the art would have found it obvious to combine these two substances into a single coating material. For a variety of reasons, which are explained below, Applicant respectfully disagrees.

I. Enteric Coatings

First, it is important to recall what is being claimed in the present application. Claim 1 of the present application recites an enteric coating formulation. Claim 1 recites that the enteric coating formulation includes an aqueous solution of shellac salt and an aqueous solution of alginate, wherein the formulation comprises between 10-90% aqueous solution of shellac salt and between 10-90% aqueous solution of alginate.

Applicant was not searching for any type of coating that could be applied to a food or pharmaceutical dose. Instead, Applicant was searching for an enteric coating. And what is claimed is an enteric coating.

It is respectfully submitted that the obviousness determination must take into account what is being claimed. Here, because Applicant is claiming an enteric coating, the question is whether the prior art references disclose materials that one of ordinary skill in the art would have found obvious to combine in order to make an enteric coating.

An enteric coating must resist the action of enzymes and fluids in the stomach, but readily dissolve in the upper intestine. Consequently, enteric coating materials must be acid resistant, thereby protecting the encapsulated dosage unit from being released in the stomach. However, the coating must dissolve or disintegrate in the neutral or mildly alkaline conditions that exist in the GI tract just after the stomach.

The normal pH of the portions of the GI tract are as follows: stomach pH 1-5, duodenum pH of 5.5 or greater, jejunum pH 6-7, ileum pH up to 7.5, colon pH 6-7. Coatings that dissolve or disintegrate to release an encapsulated dosage when the pH is around 6.0 are suitable as enteric coatings, because this results in the dosage being released when the pharmaceutical has passed through the stomach and entered the duodenum. In contrast, a coating that dissolves or

disintegrates only after the pH has been raised above 7.2 would not be considered a suitable enteric coating because the coating would prevent the dosage from being released until after the pharmaceutical has passed into the ileum.

A. Shellac Is Not Suitable For Use As An Enteric Coating

Although the Cook reference states that Shellac can be used as an enteric coating, this is not the case. As explained in Applicant's last response, subsequent to the time when the Cook patent issued, the use of shellac as an enteric coating was discredited. Applicant has already provided the Examiner with a portion of the *Handbook of Pharmaceutical Excipients*, 3rd Edition. Under Section 19 of that extract, on pages 463 and 464, the Handbook indicates that shellac is not considered a suitable enteric coating.

Applicant also refers the Examiner to paragraph 10 of the disclosure in U.S. Patent Publication No. 2011/0002986 to Durig et al. As explained therein, in its natural state, shellac is generally not soluble below a pH of 7.5 to 8.0. And if a coating of shellac will not dissolve until the pH is raised to 7.5, the shellac coating cannot be effectively used as enteric coating. The Durig patent publication also notes that shellac is normally not soluble in water.

B. Alginate Is Not Suitable For Use As An Enteric Coating

Alginates are typically insoluble only at a pH of 3.0 or less. If the pH is raised above approximately 3.0, alginate will dissolve or disintegrate. Thus, a coating made of alginate would readily dissolve in the stomach. For these reasons, those of ordinary skill in the art would know that alginate cannot be used as an enteric coating.

C. Not Obvious To Combine Shellac and Alginate to Form An Enteric Coating

Because those of ordinary skill in the art, at the time of the invention, would have known that both shellac and alginate are unsuitable as enteric coatings, those of ordinary skill in the art would have had no reason to combine these two materials to form an enteric coating. In fact, given what was known about these two materials at the time of the invention, one of ordinary skill in the art would have had every expectation that a coating material that includes both of these materials would be a failure as an enteric coating material. For at least these reasons, it is respectfully submitted that the combination of Cook and Nivaggioli is improper, and that claim 1 is allowable.

II. Difficulty in Making A Shellac-Alginate Solution

As noted above, those of ordinary skill in the art know that shellac is generally not soluble in an aqueous solution. Instead, it is usually necessary to dissolve shellac in an organic solvent, such as ethanol. In contrast, alginate and sodium alginate are water soluble.

Because the two substances must be dissolved in different substances, one of ordinary skill in the art would have known that it would be very difficult to create a solution that includes both substances, so that the solution could then be used to form a coating material. In other words, it would not have been obvious to select two materials that do not have a common solvent, and are therefore soluble in incompatible solvent systems, and still have any reasonable expectation that a mixture of these two materials would form a suitable coating with the pH requirements of an enteric coating. For these additional reasons, it is respectfully submitted that the combination of Cook and Nivaggioli is improper and that claim 1 is allowable.

III. Nivaggioli Does Not Teach That Alginate Should Be Mixed With Shellac

The Office Action appears to argue that:

1. Cook teaches that a coating made with shellac will provide an improved appearance;
2. Nivaggioli teaches that a coating made with sodium alginate provides a better “mouth feel.”
3. Therefore, one of skill in the art would have made a coating with both shellac and sodium alginate to provide both a good appearance and a better mouth feel.

To begin with, Applicant respectfully disagrees that sodium alginate provides a better mouth feel. In this context, a better mouth feel equates with being less tacky. And a careful reading of Nivaggioli reveals that coatings made with sodium alginate do not provide a better mouth feel. Instead, coatings made with sodium alginate hydrate rapidly when placed in a patient’s mouth and become tacky. See Nivaggioli at column 5, lines 11-15.

In contrast, Nivaggioli teaches that a coating made with gellan gum does provide an attractive mouth feel. When tablets with a coating made of gellan gum are placed in a patient’s mouth, the tablets become slippery and are not tacky. See Nivaggioli at column 5, lines 16-20.

Moreover, Applicant notes that Nivaggioli provides no teaching or suggestion about what would occur if sodium alginate were added to shellac to form a coating. Nivaggioli clearly did not contemplate any such combination of ingredients. Thus, Nivaggioli cannot be relied upon for a teaching that adding sodium alginate to a shellac coating would produce a coating with an improved mouth feel.

Because Nivaggioli does not provide a teaching or suggestion that adding alginate or sodium alginate to a shellac coating would improve the mouth feel of a shellac coating, and because Nivaggioli itself actually teaches that a coating of sodium alginate will result in a tacky and unpleasant mouth feel, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to form an enteric coating from these two substances. For these additional reasons, it is respectfully submitted that the combination of Cook and Nivaggioli is improper, and that claim 1 is allowable.

IV. No Other Reasons To Combine Shellac and Alginate

Finally, the Office Action appears to argue that because shellac and alginate are both known as coatings for foods and pharmaceutical doses, it would be prima facie obvious to combine these two materials to form a coating. Here again, Applicant respectfully disagrees.

As explained above, although both shellac and alginate are known as coating materials, their respective properties are quite different.

Shellac is a natural resinous material that is brittle in nature. It is not normally soluble in water, instead requiring an organic solvent. Further, it will only dissolve at a pH of 7.3 or greater.

In contrast, alginate is a viscous material. It is soluble in water. Further, it dissolves at a pH of only about 3.0

In light of the clear differences between these materials, there is no reason that one of ordinary skill in the art would have reason to believe that these materials could be mixed together to form an effective coating for a pharmaceutical or food, let alone an enteric coating that must exhibit very specific properties. In fact, everything that one of ordinary skill in the art would know about these two materials would suggest that they could not be combined to create an effective enteric coating.

In view of all of the foregoing, withdrawal of the rejection is respectfully requested.

V. CONCLUSION

It is respectfully submitted that the application is in condition for allowance. If the Examiner believes that additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

The Commissioner is authorized to charge the undersigned's deposit account #14-1140 in whatever amount is necessary for entry of these papers and the continued pendency of the captioned application.

Respectfully submitted,

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